Complete Summary

GUIDELINE TITLE

Ultrasonography in pregnancy.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Ultrasonography in pregnancy. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2004 Dec. 10 p. (ACOG practice bulletin; no. 58). [34 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

 $\begin{tabular}{ll} METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS \end{tabular}$

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

- Pregnancy
- Fetal growth and viability
- Fetal growth abnormalities
- Fetal anomalies

GUIDELINE CATEGORY

Counseling Evaluation Management Technology Assessment

CLINICAL SPECIALTY

Obstetrics and Gynecology Radiology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To present evidence regarding methodology, indications, benefits, and risks of obstetric ultrasonography in specific clinical situations

TARGET POPULATION

Pregnant women

INTERVENTIONS AND PRACTICES CONSIDERED

Ultrasonography in pregnancy

MAJOR OUTCOMES CONSIDERED

- Cost-effectiveness of ultrasonography
- Sensitivity and specificity of ultrasound for identification of fetal abnormalities

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and September 2004. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- **I**: Evidence obtained from at least one properly designed randomized controlled trial.
- **II-1**: Evidence obtained from well-designed controlled trials without randomization.
- **II-2**: Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- **II-3**: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- **III**: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician—gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

COST ANALYSIS

Several studies conducted between 1985 and 1994 found routine ultrasound screening yielded no consistent impact on perinatal morbidity or mortality. In the screened populations, the detection rate for congenital anomalies ranged from 16% to 85%. A subsequent secondary analysis of these studies concluded that routine screening was cost-effective. Using a mathematical model to evaluate further the published study results, other researchers concluded that routine screening at tertiary centers would be cost-effective, but screening in nontertiary centers resulted in a net loss.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

Conclusions

- Ultrasound examination is an accurate method of determining gestational age, fetal number, viability, and placental location. Gestational age is most accurately determined in the first half of pregnancy.
- The ability of ultrasonography to diagnose major fetal anomalies is well established.

- The diagnosis of fetal growth abnormalities with ultrasonography is not precise.
- Ultrasonography is safe for the fetus when used appropriately.
- Specific indications are the best basis for the use of ultrasonography in pregnancy.
- The optimal timing for a single ultrasound examination in the absence of specific indications for a first-trimester examination is at 16-20 weeks of gestation.

Summary of Recommendations

The following recommendation is based on limited or inconsistent scientific evidence (Level B):

• Serial ultrasonograms to determine the rate of growth should be obtained approximately every 2 to 4 weeks.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- Casual use of ultrasonography, especially during pregnancy, should be avoided.
- Before an ultrasound examination is performed, patients should be counseled about the limitations of ultrasonography for diagnosis.

Definitions:

Grades of Evidence

- **I**: Evidence obtained from at least one properly designed randomized controlled trial.
- **II-1**: Evidence obtained from well-designed controlled trials without randomization.
- **II-2**: Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- **II-3**: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- **III**: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Levels of Recommendations

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of ultrasonography in pregnancy

POTENTIAL HARMS

- Ultrasound transducers, like any instrument used on a patient, present the
 possibility of microbial transmission if not properly cleaned between patients.
 Transabdominal ultrasonography is not completely free of this risk, although
 the risk is substantially lower than it is for endovaginal ultrasonography.
 Transabdominal transducers may be adequately cleansed between patients
 simply by wiping with a disposable antiseptic paper towelette. Endovaginal
 transducers should always be covered with a single-use disposable latex or
 nonlatex cover. However, disposable protective covers are not without risk of
 rupture or defect, and it is recommended that endovaginal transducers
 undergo appropriate antimicrobial cleansing, if not chemical sterilization,
 between uses.
- From a medical standpoint, fetal ultrasonography is considered safe when
 properly used and when medical information about a pregnancy is needed;
 however, ultrasound energy delivered to the fetus cannot be assumed to be
 completely innocuous. Diagnostic levels of ultrasonography can produce
 physical effects, such as mechanical vibrations (referred to as cavitation), or
 an increase in tissue temperature under laboratory conditions.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the

needs of the individual patient, resources, and limitations unique to the institution or type of practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Patient Resources

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness Patient-centeredness Safety Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Dec

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society American College of Radiology - Medical Specialty Society American Institute of Ultrasound in Medicine - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Portions of this document were developed collaboratively by the American College of Radiology, the American Institute of Ultrasound in Medicine, and the American College of Obstetricians and Gynecologists (ACOG). Sections of the document addressing physician qualifications and responsibilities, documentation, quality control, infection control, and patient education are recommendations of ACOG.

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUIDELINE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Obstetrics

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

The following is available:

• Ultrasound exams. Atlanta (GA): American College of Obstetricians and Gynecologists (ACOG); 2006.

Electronic copies: Available from the <u>American College of Obstetricians and</u> Gynecologists (ACOG) Web site.

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

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NGC STATUS

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